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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/530,233	04/26/2000	PHILIPPE SEGUELA	641050.90021	3952

26710 7590 02/09/2004

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EXAMINER
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PAK, MICHAEL D

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 02/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 09/530,233	Applicant(s) SEGUELA ET AL.	
	Examiner Michael Pak	Art Unit 1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 20 August 2003.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 16-37 is/are pending in the application.  
     4a) Of the above claim(s) 22-33 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 16-21 and 34-37 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
     a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Response to Amendment***

1. Amendment filed 20 August 2003 has been entered. Claims 16-37 are pending. Claims 22-33 are withdrawn as drawn to non-elected claims.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
3. Applicant's arguments filed 20 August 2003 have been fully considered but they are not found persuasive.
4. This application contains claims 22-33 drawn to an invention nonelected with traverse in Paper filed 22 July 2002. A complete reply to the final rejection must include cancelation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

### ***Claim Objections***

5. Claims 34-37 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

Claims 34-37 are dependent on claim 16 which is drawn to a narrower claim limitation of SEQ ID NO:2 whereas the dependent claims encompass the percent identity to SEQ ID NO:2.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 16-22 and 34-37 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 16 encompasses a channel having the amino acid sequence of SEQ ID NO:2 which is confusing because a channel is composed of subunits and it is not clear how a channel has the SEQ ID NO:2. It is suggested that the claims be amended to recite "An isolated proton-gated cation channel comprising a subunit which comprises the amino acid sequence of SEQ ID NO:2." The dependent claims 17-22 and 34-37 are confusing because the dependent claims are generic to the parent claim 16 and it is not clear how the channel can be constructed from a single channel with SEQ ID NO:2 to a generic channel.

7. Claims 34-37 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the

application was filed, had possession of the claimed invention. This is both a new matter and written description rejection.

The claims recite “at least 90% identity with the amino acid sequence of SEQ ID NO:2”, “at least 95% identity with the amino acid sequence of SEQ ID NO:2”, “at least 98% identity with the amino acid sequence of SEQ ID NO:2”, and “at least 99% identity with the amino acid sequence of SEQ ID NO:2” which is new matter because the subgeneric limitation is not disclosed in the specification.

The claims encompass channel comprising variant channel because of the percent identity limitation without a functional limitation. However, the specification does not adequately disclose the claimed genus of variants. However, the specification only discloses a species of channel subunit of SEQ ID NO:2 with a specific function but do not disclose a genus of other channels without a functional limitations. *University of California v. Eli Lilly and Co. (CAFC) 43 USPQ2d 1398* held that a generic claim to human or mammalian when only the rat protein sequence was disclosed did not have written description in the specification. The essential feature of the invention is the channel subunit of SEQ ID NO:2 with the specific function. It is suggested that specific functional limitations be included in the claims.

8. Claims 16-21 and 34-37 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated channel comprising the subunit with an amino acid sequence of SEQ ID NO:2, does not reasonably provide enablement for the claimed channel. The specification does not enable any person

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skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Claim 16 encompasses a channel having the amino acid sequence of SEQ ID NO:2. However, the specification does not teach how to make and use the claimed channel because a channel is composed of subunits and it is not clear how a channel has the SEQ ID NO:2. It is suggested that the claims be amended to recite "An isolated proton-gated cation channel comprising a subunit which comprises the amino acid sequence of SEQ ID NO:2." Claims 17-21 are dependent on claim 16.

The claims 34-37 encompass a variant channel which is non functional because of the percent identity claim limitations but without a functional limitation. However, the specification does not teach how to make and use an ion channel which is not functional. Changes in the transmembrane and ion pore domains are unpredictable because one skilled in the art at the time of the invention could not determine which amino acid changes to the domain would be functional without further experimentation. It would require undue experimentation to determine the effect of random mutations because functional domains of proteins require proper protein conformation and the prediction of protein conformation based on primary amino acid sequence is unpredictable (Bowie et al., Science (U)). Such determination requires empirical experimentation to determine the amino acids changes which are functional and non-functional. Thus, sequence similarity alone without function is insufficient to support claims to polypeptide other than the disclosed sequence where the genus includes

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inactive proteins. Without such guidance the experimentation necessary to make and use the variants, derivatives, and fragments is undue.

9. No claims are allowed.

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Pak whose telephone number is 571-272-0879. The examiner can normally be reached on 8:30 am - 2:00 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on 571-272-0871. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9306 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-0507.

*Michael D. Pak*

Michael Pak  
Primary Examiner  
Art Unit 1646  
February 8, 2004